

Attachment 1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Damir et al.

Attorney Docket No. SWAD-1-
1002

Serial No.: 10/751,070

Group Art Unit: 3765

Filing Date: January 2, 2004

Examiner: Gloria HALE

Title: SWADDLING BLANKET

DECLARATION OF LYNETTE DAMIR, RN

TO THE COMMISSIONER OF PATENTS:

Lynette Damir, RN, does declare the following to be true:

I am the inventor of the invention taught in the subject application, have expertise in the field of newborn care with a focus on swaddling as a technique for calming and comforting newborns, and make the following statements that are true and accurate to the best of my knowledge:

I have been formally trained as a registered nurse and have been involved in the care of newborns both within and outside of the hospital setting. I have been formally trained in the care of newborns and the practice of swaddling. I have been a licensed and registered nurse since 1987. As a student nurse I conducted my first family visit in 1986 and instructed new parents per their request on swaddling technique because they could not remember how the nurses swaddled their baby at the hospital.

I have read extensively on the subject of swaddling including, but not limited to, the following: The Essentials of Pediatric Nursing by Whaley and Wong, The American Academy of Pediatrics Caring for Your Baby and Young Child, Birth to Age 5 by Steven Shelov MD, FAAP, Editor-in-Chief, Your Baby and Child by Penelope Leach, Babyhood by Penelope Leach, The Happiest Baby on the Block by Dr. Harvey Karp, Pregnancy, Childbirth and the Newborn by Simkin, Whalley and Keppler, Helping Your Child Sleep Through the Night by Cuthbertson and

Schevill, *Sleeping Through the Night* by Jodi Mindell, *Nighttime Parenting* by William Sears, *Developmental Care of Newborns & Infants - A guide for Health Professionals* by Kenner and McGrath, *Gentle Baby Care* by Elizabeth Pantley, *The No Cry Sleep Solution* by Elizabeth Pantley, *The Baby Book* by Sears and Sears, *Touchpoints* by T. Berry Brazelton, MD, *Touch: The Foundation of Experience* by Barnard and Brazelton, *Journal of Pediatrics* 2002, 2006, *Child Development* 1989, *Pediatrics* 2002, 2005, The American Academy of Pediatric website, The Consumer Products Safety Commission website. The National Institute of Child Health and Human Development website.

I have interviewed and surveyed new and experienced parents locally, across the USA, Canada, UK, Mexico, Spain, Korea, Australia and New Zealand to seek a deeper understanding of swaddling practices across different social and economic groups of parents.

During my research, I consulted with PhDs in the field of infant research including: Dr. Kathryn Barnard PhD, FAAN, Winner of the Gustav O. Lienhard award and leading infant researcher, regarding hand position when swaddling; Pamela Jordan, PhD, RN, Associate Professor School of Nursing at University of Washington, and Developer of The Becoming Parents Program, regarding proper swaddling technique for instruction for new parents; Lark Young, RN, Community Education Manager at Overlake Medical Center, Bellevue, Washington regarding proper swaddling technique for the purpose of instruction to new parents; Dr. Harvey Karp, Pediatrician, author of *Happiest Baby on the Block*; Dr. Larry Holland, Orthopedic Physician, Dr. William Wagner, Orthopedic Physician; Theresa Kledzik, RN, Developmental Nurse Specialist; Brenda Blasingame, MA, Director of Programs at the Talaris Research Institute; Penny Simkin, PT, Co- Founder of Doula's of North America, and Author of *Pregnancy, Childbirth and the Newborn*; and Tarryn Rivkin, Pediatric Occupational Therapist; and leaders of the La Leche League and CAPP.

I have provided consultation to Overlake Medical Center in Bellevue, Washington, St. Luke's Medical Center in Boise, Idaho, Group Health Cooperative Hospital in Seattle, Washington.

Prior to my invention, as a proponent for swaddling, I searched the market extensively for blankets that would aid new parents in learning how to swaddle, how to make an effective swaddle and found no blankets with swaddling instructions included with the blanket or sewn to the edge of the blanket.

I make the statements contained herein based upon my training, my experience as a caregiver, my experience as a mother of newborns, my research and my experience as the founder and CEO of SwaddleDesigns, the supplier of the swaddling blankets according to the teachings of the invention.

THE UNIQUE NATURE OF THE BLANKET

I invented the blanket that is the subject of the patent application because I perceived an intense need for such an instructional blanket when I was visiting new parents. Few, if any of the new parents knew how to properly swaddle a newborn in a fashion that would provide a secure and appropriately snug fit supporting the newborn.

SWADDLING

I have long been a believer in the practice of swaddling and make this endorsement of the practice of swaddling in contrast to the simple action of wrapping a child in a blanket. Swaddling, properly performed, is a snug wrap with distinct folds that remains secure, and prevents the newborn from startling itself awake, and most importantly, a proper swaddle will not become loose and allow the newborn to wiggle out of the blanket. If the swaddle becomes loose, then the newborn is more likely to become unsettled.



The value of swaddling has been confirmed to be beneficial by medical research culminating in a report published in December 2002. In the report, researchers at Washington University of St. Louis proved swaddled babies sleep better. The study further proved that a properly and securely wrapped baby sleeps better - with fewer awakenings and more REM sleep than unwaddled babies. The American Academy of Pediatrics recommends the back (or supine) position for infant sleep. Swaddled babies sleep for longer periods of time on their back than unwaddled babies and therefore are less likely to be placed by their parents in the unsafe stomach position for sleep. There is a 3-fold increase of SIDS with babies who are put in the stomach position for sleep. In addition, there is evidence that swaddled back sleeping infants have lower incidence of SIDS than unwaddled back sleeping infants as stated in the Journal of Pediatrics, December 2002

Many experts have opined that the snug wrap of a properly swaddled baby reminds that baby of a similar feeling to being in the womb. For that reason, the practice of swaddling eases the transition from womb to world. Swaddling contains the baby's extra movements caused by the startle reflex that can wake a sleeping baby. And, of course, when swaddled babies sleep better, the parents sleep better too.



Understanding the value of the practice of swaddling, I have completed much research to learn more about the practice. In the USA, until the middle of the twentieth century, many young women would have had the opportunity to learn swaddling in the care of siblings and of relatives. As the average sizes of families decreased, and new moms began having babies in cities away from their relatives, the knowledge of swaddling was passed to new mothers in

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hospitals. New moms, generally, stayed in the hospital for five to seven days after giving birth; during that time, they would receive much instruction on newborn care.

In the late 1980s, absent some severe complication, new moms were discharged 24 to 48 hours postpartum. With such a short postpartum stay, there is little time for teaching any skills to the new mothers, thus they very rarely learn how swaddle while at the hospital. Stabilization and recovery of the mother and baby is the central focus of the stay. New mothers are discharged with much to learn in terms of skills necessary or desirable for newborn care.

Learning swaddling has been a particular challenge to new parents. Beginners often give up as they become frustrated with swaddling because they cannot remember the steps to properly swaddle their baby. It is not obvious to new parents how to make the distinct folds to make an effective swaddle. A loosely wrapped blanket or improper swaddle does not contain the baby's extra movements caused by the startle reflex (arms and legs flail) which it then wakes the baby or the baby can kick-out of the blanket which causes the baby to wake and cry. These frustrations can quickly cause the parent to quit trying to swaddle.

FILLING AN UNMET NEED

As a nurse and a mom, I am constantly looking for aids to the care of newborn children. Given my profound regard for the practice of swaddling, I began to search the market for swaddling blankets that would help instruct new parents. After an exhaustive search, I could find no blanket that taught swaddling folding techniques and no blanket that included swaddling instructions.

My view of the need required the instructions for swaddling to be on a swaddling blanket. To make an effective swaddle one needs the right kind of blanket and proper technique. Swaddling is a learned art and a difficult one initially. I compare it to learning Origami around a wiggly baby. It is nearly impossible to hold open a book, and follow the swaddling instructions while trying to swaddle a newborn. In the middle of the night when trying to settle their baby,

new parents are not going to turn on the TV to watch a video. The invention, then, was to have the instructions on a strategic spot sewn to the edge or drawn on a suitable blanket. Using such a blanket, the steps of how to swaddle are positioned right at the caregiver's fingers tips and visible while the parent wraps the wiggling child. Instructions to the new parent are placed where they can be most effective.

OBVIOUSNESS FACTORS

THE SCOPE AND CONTENT OF THE PRIOR ART

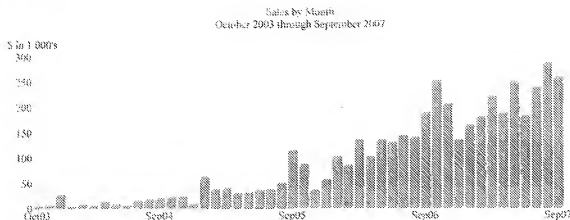
It had not been my intent to enter into the business of producing and selling swaddling blankets. Rather, my hope was to find a suitably configured blanket that I could recommend to new parents for properly swaddling their newborns. I searched the Internet and known suppliers of children's clothing and supplies. Repeated and frequent searches unearthed no blankets properly cut for swaddling. Additionally, I could find no blanket with swaddling instructions permanently sewn to it showing how to accomplish swaddling.

OBJECTIVE EVIDENCE OF NONOBVIOUSNESS (GRAHAM FACTORS)

COMMERCIAL SUCCESS

SwaddleDesigns has grown from a small start-up to reach a point of commercially shipping over 1,000 blankets per day. Over the past four years, SwaddleDesigns has commercially shipped approximately 300,000 blankets. The commercial success has resulted in sales growing by over 2000% over three years. This graph shows the progress in monthly sales of the inventive blanket that is the subject of

the application:



The market is not an easy one to enter or to remain in. The innovative nature of the invention, however, has allowed the assignee, SwaddleDesigns, to become a category leader in the baby blanket industry dominated by Carter's, Gerber and other established companies.

The sales have been to a sophisticated clientele including Nordstrom, BabyCenter, Target.com, Babystyle, BabiesRUs.com, buybuyBaby, giggle, Von Maur, and hundreds of retailers around the world who all carry the SwaddleDesigns blanket. For example, Village Maternity (an independently owned and operated upscale retail maternity and postpartum shop in Seattle, Washington since 1983) and Kid's Club (another upscale retailer in Seattle focusing on children) have carried the SwaddleDesigns blanket since 2003. The blanket appeals to buyers who understood that new parents often struggle when trying to swaddle, and they understand that the



SwaddleDesigns
Ultimate Pacifying Blanket
the only blanket
with cradling motions
sewn to its edge.



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SwaddleDesigns blanket helps new parents learn how to swaddle and comfort their newborns. Today, retailers continue to sell an increasingly higher volume of SwaddleDesigns blankets every month.

In the crowded product category of baby blankets where there is little opportunity to differentiate a product, SwaddleDesigns success bears testimony to the innovation represented by the presence of the instructive tag.

LONG-FELT BUT UNSOLVED NEEDS

When visiting new parents, I consistently found that parents often struggled when attempting to swaddle their newborns. Parents would repeatedly ask me to show them how to swaddle.

As I have stated above, in 2001 and 2002, I surveyed products on the market and I found many small rectangular receiving blankets, as well as thick or satin backed blankets; none of the available blankets were appropriate for swaddling. In addition, when looking for illustrations, in the many newborn care books available, I found very few books had illustrations showing how-to-swaddle. I interviewed and surveyed new parents and found that the vast majority didn't know how or couldn't remember how to swaddle, however they stated a desire to be shown how to swaddle like the nurse at the hospital. I believe that these factors, along with the commercial success of the blanket bear testimony to the fact that there has been a long-felt need for the inventive blanket.



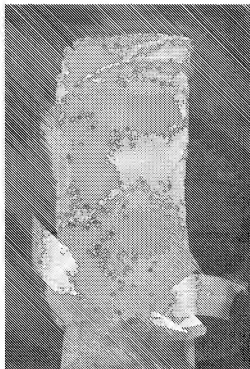
COPYING

My attorney has explained to me that there are many cases that outline the use of secondary factors to prove novelty and non-obviousness. He further explains that in several

cases, including *Allen Archery, Inc. v. Browning Mfg. Co.*, 819 F.2d 1087, 1092, 2 USPQ2d 1490, 1493 (Fed. Cir. 1987) (considering copying, praise, unexpected results, and industry acceptance as indicators of nonobviousness); and *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 679, 7 USPQ2d 1315, 1319 (Fed. Cir. 1988) (considering copying as an indicator of nonobviousness), the Courts have placed great weight upon the fact that once a product is introduced, if copying of that product occurs, the product was non-obvious.

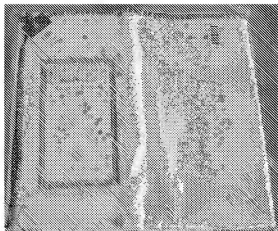
Since the introduction of the subject blanket, several have tried to duplicate it. For example, the retailer Gap was thwarted in its plans to copy SwaddleDesigns blanket. In 2005, the Gap attempted to copy SwaddleDesigns blanket. The Gap swaddle blanket was nearly identical in several ways: (i) same size (42"x42"), (ii) polka dots in the same colors as SwaddleDesigns, (iii) same decorative edge stitch, (iv) same fabric using cotton flannel.

The Gap did not include an instructional tag sewn to the edge of the blanket. A true and accurate photograph of the Baby Gap blanket is shown.



When I, at SwaddleDesigns learned of the Gap swaddle blanket, I did so because consumers sent emails to SwaddleDesigns and asked whether the Gap was copying SwaddleDesigns or whether SwaddleDesigns had partnered with the Gap. In January 2006, a letter to the Gap explaining that SwaddleDesigns was willing to protect their intellectual property in the blanket convinced the management of the Gap that it would be unwise to continue to sell the product. Within a few months after the letter, the Gap reduced the retail price twice and eventually discontinued their knock-off blanket.

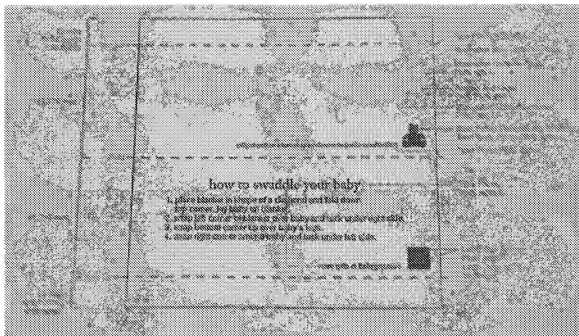
In October 2005, Babystyle, a very high-end regional maternity retailer, attempted to copy SwaddleDesigns Ultimate Swaddling Blanket® by introducing a Babystyle polka dot swaddling blanket as pictured in the true and accurate photograph. The Babystyle blanket was a large square, cotton flannel blanket with a decorative edge and included swaddling instructions in the packaging. However,



Babystyle did not attempt to copy a sewn instruction tag and did not sew instructions to the edge of the blanket. Without the inventive tag, after several months, Babystyle also reduced their blanket price a couple of times due to poor sales and eventually discontinued their product.

Based on the lack of success of their own product and the realization that the inventive tag carrying instructions on the SwaddleDesigns blanket is superior to the blanket without the tag, Babystyle decided to carry SwaddleDesigns Ultimate Swaddling Blanket®. The Babystyle blanket was polka dot, decorative edge, large square, cotton flannel, thus, virtually identical to the SwaddleDesigns Ultimate Swaddling Blanket® with the exception of the primary differentiator between the SwaddleDesigns blanket and the Babystyle blanket, the inventive, instructional tag. Today, Babystyle is one of SwaddleDesigns top 10 customers.

In 2006, there was another incident that illustrates how closely several companies are watching the SwaddleDesigns patent application. Due to an administrative error, the patent application disappeared from the USPTO publicly available web site. Within a short period of time, SwaddleDesigns learned from an unnamed source that the Gap was preparing to copy the SwaddleDesigns Ultimate Swaddling Blanket® instructional label. SwaddleDesigns was sent the Gap label artwork that was destined to Asia for production as shown below. As is apparent by inspection, the label artwork was a near-exact copy bearing the BabyGap legend instead of 123 Swaddle®. In response, SwaddleDesigns sent a letter to the Gap to inform the Gap that our



patent application was still pending. In our vigilant monitoring of the Gap, I can assure you that they have not sold the blanket with the label as shown above.

PRAISE

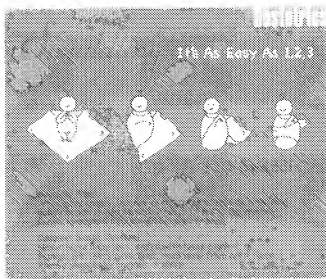
Another factor in *Allen Archery, Inc. v. Browning Mfg. Co.*, 819 F.2d 1087, 1092, 2 USPQ2d 1490, 1493 (Fed. Cir. 1987) (considering copying, praise, unexpected results, and industry acceptance as indicators of nonobviousness) was praise for the invention.

The first customer for the SwaddleDesigns Ultimate Receiving Blanket® was a major hospital in the Seattle area known as Overlake Regional Medical Center. In making the decision to purchase 4,000 blankets each to serve as a departure gift for their new parents, the hospital's management explained that they were very impressed with the educational value of attached instructions for swaddling. The manager of Family and Community Education for the Women Clinical Services department sponsored the program with the support of the hospital's Director. To amplify the expected success of the program, the leadership of the hospital included an article praising the blanket in their quarterly newsletter in 2004.

During the development of the blanket, I met with Pamela Jordan, PhD, RN, Professor School of Nursing at University of Washington. Dr. Jordan is the developer of The Becoming Parents Program, a couple-focused educational program for couples adding a new baby to the family through birth, adoption, or foster parenting. The program teaches survival skills for taking care of their relationship, relating and caring for their baby, and dealing with the many ways that adding a new baby to the family impacts their lives.

I was introduced to Dr. Jordan by Lark Young, RN, Manager of Family and Community Education at Overlake Regional Medical Center. Prior to the final approval of the educational blanket gift program, Overlake management requested expert review and opinion from Dr. Jordan and her colleagues at University of Washington.

As a medical professional and researcher who has studied the challenges new parents face as they transition to parenthood, Dr. Jordan is an expert in the field. She immediately understood and communicated that the swaddling instructions on the tag would be very helpful to new parents. She stated, "You have a great idea that will help many, many new parents." Furthermore, she stated "she was pleased that a fellow nurse had invented such a wonderful, practical, and educational product."



The 1st As Easy As 1, 2, 3 is a book that provides a comprehensive guide to the first year of a child's life. It covers everything from pregnancy and childbirth to the first year of a child's life, including feeding, sleeping, and playing. The book is written in a clear, concise, and easy-to-read style, making it a valuable resource for new parents. It is available in paperback for \$14.95.

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Dr. Jordan shared the design concept with her colleagues and after their collective review, she communicated to me that she would provide Overlake Regional Medical Center with very positive feedback. Soon after, Overlake Regional Medical Center made their first purchase of 4,000 blankets and over the following years, Overlake Regional Medical Center purchased over 10,000 blankets.

When showing my inventive blanket with the instructional tag to individuals who have recently had a baby and especially if they experienced frustration when trying to learn how to swaddle, they typically exclaim, "What a great idea!", "I wish I had this blanket when my son was a baby!" "I love it!" "Where can I buy one, I want to give one to my friend who is expecting." When showing the inventive blanket with the tag sewn into the edge of our blanket to retail buyers, pediatricians, nurses, doulas, parent educators, lactation consultants, or OBs, I have come to expect very similar results. Uniformly, their eyes light up, a smile emerges, they point at the tag and state an enthusiastic positive exclamation such as, "THAT is ingenious!", "How great is THAT!", "THAT is wonderful!", and "What a GREAT idea!" I assert, consistent with the court in *Allen Archery*; that if the blanket weren't novel and non-obvious, people would not consistently react with positive, surprised, and delighted response.

As I have truthfully declared in the facts set forth above, every of the relevant *Graham* factors that applies to the pending application clearly militates for the non-obvious nature of the invention. The current rejection fails to recognize the novel nature of the invention and has been notably and unduly prolonged. Given the clear and unequivocal evidence I present in this declaration, I believe that there can be no reasonable doubt that the *Graham* factors allow for but one reasonable conclusion, that the invention is novel and non-obvious. If the Examiner is in need of further information, I remain at his or her service and will provide, through my attorney of record, declarations and evidence that further proves the non-obvious nature of the invention.

I, Lynette Damir, declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated this 3rd day of December, 2007.

A handwritten signature in dark ink, appearing to read "Lynette Damir", written over a horizontal line.